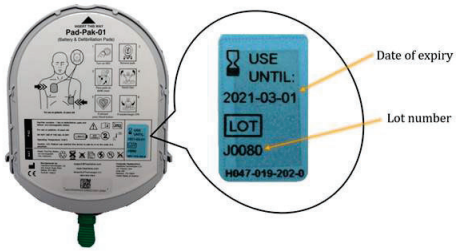
Urgent Field Safety Notice: RA2023-3293631

August 2023

Affected Products

GTIN	Product Description		Lot Numbers
N/A	350-BAC-BZ-10	450-BAS-JA-08	A3517 A3518 A3519 A3547 A3548 A3553 A3554 A3555 A3556 A3557 A3558 A3559 A3560 A3561 A3563
	350-BAS-JA-08	500-BAS-AS-10	
	350-STR-US-10	500-BAS-CN-10	
	360-BAS-AS-10	PAD-PAK-01	
	360-BAS-CF-10	PAD-PAK-03	
	360-BAS-CN-10	PAD-PAK-03J	



Product description

The Pad-Pak is a single use battery and electrode cartridge containing the battery to power the HeartSine samaritan PAD (LiMnO2 (18V – 1500mAh) non-rechargeable battery) and two electrode pads to provide the electrical connection for delivery of defibrillation to the patient's chest.

Product issue

Stryker is expanding its voluntary recall as we have determined that the affected Pad-Paks may be rendered inoperable due to depleted battery cells. As a result, the affected Pad-Paks could potentially fail to power on the device if needed for use.

Potential risks

The issue could prevent device from analyzing patient condition or delivering therapy correctly. **To date, there have been no reports of adverse events.** Stryker has received 7 complaints associated to this issue, but no patient involvement.

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Stryker's planned actions:

The company is notifying all customers that have received HeartSine devices that may have the affected Pad-Paks.

Customer actions needed:

1. Inspect your Pad-Pak inventory to identify if you have any of the affected lot numbers listed on page 1.
    a. If affected Pad-Paks are found, please request replacement by emailing XXXX.
2. Complete the attached business reply form below (Attachment 1) and return it by email to XXXX confirming your receipt and understanding of this information.
    a. Upon receipt of the acknowledgment form, Stryker will arrange for the shipment of replacement Pad-Pak(s) at no charge to you.
3. In the interim, please continue monitoring the AED to ensure the status indicator is flashing green every 5 to 10 seconds. Please contact your Authorized Distributor or HeartSine Technologies immediately if you identify either of the following situations:
    a. If the status indicator is flashing red or you hear continuous beeping.
    b. If there is no status indicator operative.
4. Once you receive the replacement Pad-Paks, please destroy the affected Pad-Paks per local disposal guidelines.
5. Maintain awareness of this communication internally until the required action has been completed within your facility.
6. Inform Stryker if any of the subject Pad-Paks have been distributed to other organizations.
    a. If further distributed, please send an email to XXXX notifying Stryker of further distribution.
    b. Please use attached Customer Letter (Attachment 2) to notify your customers immediately and collect all responses and send it to XXXX. Stryker will work with you to ensure recipients are notified appropriately.

We request that you respond to this notice within XXX calendar days from the date of receipt. *Please respond event if you do not have a record of receiving affected inventory. This will enable us to update our records and negate the need to send unnecessary reminder letters.*

Your designated contact person for this action is given below. Should you have any queries concerning this matter please do not hesitate to contact them directly.

Name: Position: email:

In line with the recommendations of the Meddev Vigilance Guidance document Ref 2.12-1 and EU 2017/745, we can confirm that this FSCA has been notified appropriately to the National Competent Authority for your country.

On behalf of Stryker we thank you sincerely for your help and support in completing this action within the target date and regret any inconvenience that may be caused. We would like to reassure you that Stryker is committed to ensuring that only conforming devices, meeting our high internal quality standards, remain on the market.

Sincerely,

XXXX

Attachment:

- Attachment 1: Business Reply Form
- Attachment 2: Example Customer Letter

Attachment 1: Business Reply Form

Business Reply Form- response required

HeartSine samaritan® PAD (Public Access Defibrillator)350P/360P/500P

Account #
Recall Number: RA2023-3293631
August 2023

Response is required:
Please complete and sign this form by XXXX. Return the completed form by email to XXXX.

The quantities indicated below will be replaced upon receipt of this acknowledgment form. This form must be returned in order to receive replacement product.

Lot Number(s)	Quantity

If you have further distributed any affected product, please indicate to whom:

Product(s) Distributed			
Facility Name		**Contact Person**	
Full Address			

Form completed by:

Printed Name		**Title**	
Signature		**Phone**	
Date		**Email**	

Note: *Your signature indicates that you have received and understand the enclosed notification and that you have destroyed all items identified.*

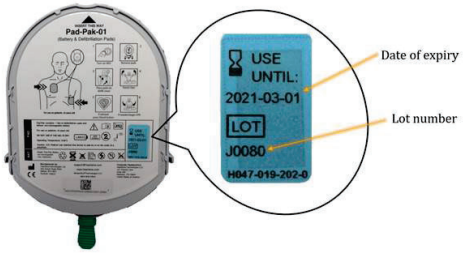
Attachment 2: Example Customer Letter

Urgent Field Safety Notice: RA2023-3293631

Recall Number: RA2023 -3293631

Affected Products: **HeartSine samaritan® PAD (Public Access Defibrillator) 350P/360P/450P/500P**

GTIN	Product Description		Lot Numbers
N/A	350-BAC-BZ-10 350-BAS-JA-08 350-STR-US-10 360-BAS-AS-10 360-BAS-CF-10 360-BAS-CN-10	450-BAS-JA-08 500-BAS-AS-10 500-BAS-CN-10 PAD-PAK-01 PAD-PAK-03 PAD-PAK-03J	A3517 A3518 A3519 A3547 A3548 A3553 A3554 A3555 A3556 A3557 A3558 A3559 A3560 A3561 A3563



Product description The Pad-Pak is a single use battery and electrode cartridge containing the battery to power the HeartSine samaritan PAD (LiMnO2 (18V – 1500mAh) non-rechargeable battery) and two electrode pads to provide the electrical connection for delivery of defibrillation to the patient's chest.

Product issue Stryker is conducting a voluntary recall as we have determined that the affected Pad-Paks may be rendered inoperable due to depleted battery cells. As a result, the affected Pad-Paks could potentially fail to power on the device if needed for use.

Potential risks The issue could prevent device from analyzing patient condition or delivering therapy correctly. **There have been no reports of adverse events to date.**

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Planned Actions:

The company is notifying all customers that have received HeartSine devices that may have the affected Pad-Paks.

Customer actions needed:

1. Inspect your Pad-Pak inventory to identify if you have any of the affected lot numbers listed on page 1.
    a. If affected Pad-Paks are found, please request replacement by emailing XXXX.
2. Complete the attached acknowledgment form below (Attachment 1) and return it by email to XXXX confirming your receipt and understanding of this information.
    a. Upon receipt of the acknowledgment form, Stryker will arrange for the shipment of replacement Pad-Pak(s) at no charge to you.
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We request that you respond to this notice within XXX calendar days from the date of receipt.
Please respond event if you do not have a record of receiving affected inventory. This will enable us to update our records and negate the need to send unnecessary reminder letters.
Your timely response will enable us to update our records and negate the need to send reminder notices.

Your designated contact person for this action is given below. Should you have any queries concerning this matter please do not hesitate to contact them directly.

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In line with the recommendations of the Meddev Vigilance Guidance document Ref 2.12-1 and EU 2017/745, we can confirm that this FSCA has been notified appropriately to the National Competent Authority for your country.

On behalf of Stryker we thank you sincerely for your help and support in completing this action within the target date and regret any inconvenience that may be caused. We would like to reassure you that Stryker is committed to ensuring that only conforming devices, meeting our high internal quality standards, remain on the market.

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Attachment:

- Attachment 1: Acknowledgment Form